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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/651,563 | 08/29/2000 | Tongtong Wang | 210121.478C10 | 1478 |
| 7590 | 01/02/2004 | | EXAMINER | |
| Jane E R Potter Seed Intellectual Property Law Group PLLC 701 Fifth Avenue Suite 6300 Seattle, WA 98104-7092 | | | BORIN, MICHAEL L | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1631 | |
| DATE MAILED: 01/02/2004 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

| Application No. | Applicant(s) |
|-----------------|--------------|
| 09/651,563 | WANG ET AL. |
| Examiner | Art Unit |
| Michael Borin | 1631 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 20 August 2003.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 61-63 and 67-69 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 61-63 and 67-69 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) The translation of the foreign language provisional application has been received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____.
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) Other: _____

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DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 09/10/2002 has been entered.

Status of Claims

2. Claims 1-3,11-60,63-65 are canceled. Claims 62,66,67 are amended. Claims 61,62,63,67-69 are pending.

Claim Rejections - 35 USC § 112, first paragraph.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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3. Claims 62, 67,68 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claim 62 introduces new matter as it recites subgenus of polynucleotides that are having at least 90% degree of identity with SEQ ID NO: 808 and are hybridizable to SEQ ID NO: 808 under moderately stringent conditions. Such subgenus is not disclosed in the specification.

4. Claims 62,67,68 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The claims are drawn to polynucleotides having at least 90% degree of identity with SEQ ID NO: 808, wherein the polynucleotides can be used in the detection of cancer. The specification discloses SEQ ID NO: 808 which corresponds to the cDNA encoding protein SEQ ID NO: 69 (referred to as L552S), and is overexpressed in lung tumor tissue. Polynucleotide SEQ ID No. 808 itself meets the written description and enablement provisions of 35 USC 112, first paragraph. However, claim 62 is drawn to nucleotide sequences having more than 90% identity

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to the elected SEQ ID 808, does not have sufficient description in the specification as description of species is insufficient to support a highly variable genus. Applicant is advised that absent factual evidence, a percentage sequence similarity of less than 100% over the entire length is not deemed to reasonably support to one skilled in the art whether the biochemical activity of newly discovered sequence would be the same as that of similar known biomolecule. Further, in regard to polynucleotides that can be used in the detection of polynucleotide SEQ ID No. 808 itself there is no information in the specification on the sequence requirements for such polynucleotides to be selective in detection this particular polynucleotide without false detecting others. Accordingly, the specification does not provide a written description of the invention of claim 62, and, consequently, of its expression cell and vector of claims 67,68. The specification provides insufficient written description to support the genus encompassed by the claim.

Therefore, only SEQ ID NO: 808 but not the full breadth of the claim meets the written description provision of 35 USC 112, first paragraph.

Response to arguments

Applicants assert that "it is absolutely understood that polynucleotides having significantly less than 100% identity to the polynucleotide can be specifically

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hybridize to and be used to detect a particular polynucleotide". Examiner disagrees. While a "polynucleotides having significantly less than 100% identity" will hybridize to the original polynucleotide, the specificity of such binding is not granted, and there is no information in the specification on the sequence requirements for such polynucleotides to be selective in detection this particular polynucleotide without false detecting others.

5. Claims 66,67,68 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Similarly to the discussion of polynucleotides having at least 90% degree of identity with SEQ ID NO: 808 above, claim 66, drawn to polynucleotides hybridizable to SEQ ID NO: 808 under moderately stringent conditions,, does not have sufficient description in the specification as description of species is insufficient to support a highly variable genus. The only product disclosed in the specification is the protein SEQ ID No. 808 itself. There is no disclosure of other polynucleotides hybridizable to SEQ ID No. 808 or guidance of a core structure required for such polynucleotides to

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be either overexpressed in lung tissue or usable for specific determination of SEQ ID No. 808. Patent specification must describe claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention.

6. Claims 69,67,68 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Similarly to the discussion of polynucleotides having at least 90% degree of identity with SEQ ID NO: 808 above, claim 69, drawn to polynucleotides having at least 175 residues of SEQ ID No. 808, does not have sufficient description in the specification as description of species is insufficient to support a highly variable genus. The only product disclosed in the specification is the protein SEQ ID No. 808 itself. Neither fragments, or guidance for core structure required for the fragments, or other polynucleotides comprising said fragments to be either overexpressed in lung tissue or usable for specific determination of SEQ ID No. 808 are present. Patent specification must describe claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention.

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Conclusion.

7. Claim 61 is allowed, as was previously indicated.
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

July 12, 2002

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

mlb

